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10/554,703	10/09/2006	Susanne Lang-Fugmann	9741-014-999	9359

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JONES DAY
222 East 41st Street
New York, NY 10017-6702

EXAMINER

KASSA, TIGABU

ART UNIT	PAPER NUMBER
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1619

MAIL DATE	DELIVERY MODE
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07/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/554,703	Applicant(s) LANG-FUGMANN, SUSANNE	
	Examiner TIGABU KASSA	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/20/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4, 6, and 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

Applicant's amendments filed 04/20/2010 are acknowledged and entered. **Claims 1-2, 4, 6, and 9-15 are pending. Claims 1-2, 4, 6, and 9-15 are under consideration in the instant office action.** Claims 3, 5, and 7-8 are cancelled. This Office Action is FINAL.

Rejections Withdrawn

The rejections applied in the previous office action under 35 U.S.C. 112, second paragraph are hereby withdrawn as a result of applicant's amendments.

Rejections Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 1-2, 6, and 9-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Samour et al. (US Patent No. 6,224,887) in view of Ippen et al. (US Patent No. 4,956,370), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicant's arguments filed on 04/20/2010 have been fully considered but they are not persuasive.

Applicant argues that there would have been no "reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does." Samour describes "antifungal nail lacquer compositions" comprising: (1) at least one antifungal agent; (2) penetrating enhancers selected from the group consisting of CT-C14-hydrocarbyl substituted 1,3-dioxolane, C7-C 14-hydrocarbyl substituted 1,3- dioxane and C7-C14-substituted acetal; (3) film-forming polymer; and (4) volatile solvent. (Samour, col. 3, lines 13-28). However, "examples of suitable antifungal agents" described in Samour do not

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include those disclosed in Ippen. Consequently, absent any disclosure in Samour that the antifungal agents described therein are disadvantageous for some reason, those skilled in the art reading Samour would not have had any reason to consider using any other antifungal agent than those described in Samour.

The examiner respectfully disagrees with applicant's assertions because for Ippen to be a proper prior art it does not necessarily have to teach the specific antifungal agents taught by Samour. Ippen need not teach what is taught by Samour. The examiner has established the fact that the nail lacquer composition of Samour incorporates antifungal agent and **Ippen et al. teach that pharmaceutical composition comprising substituted 2-aminothiazol that can be used for the treatment, prevention, amelioration and/or cure of mycoses (column 21, lines 26-27) either dermatomycoses and systemic mycoses (column 19, lines 32-33)** (which includes nails). Additionally, an express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. See, *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

The examiner also notes that the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In the instant case, both references teach the incorporation of antifungal agent and the suitability of the antifungal agents is conventionally known and understood to be imparting an antifungal effect. Therefore, substituting one antifungal agent with another antifungal agent known to impart the same effect is sufficient to establish a *prima facie* case of obviousness. Additionally, the examiner also notes that applicant is resorting to attacking the references individually, rather than responding to the

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combination of references as recited in the rejection. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant also asserts that there would have been no predictability as to the properties of the formulation resulting from combining Samour and Ippen, i.e., no reasonable expectation of success. As pointed out above, Samour's description of exemplary antifungal agents does not include those compounds described in Ippen. Although it is alleged in the Office Action that it would have been obvious to replace the antifungal agents described in Samour with those described in Ippen because "both antifungal agents are functionally equivalent," Applicant respectfully submits that such a contention is scientifically incorrect. This is because, even if the allegation made in the Office Action regarding "functional equivalence" were true, such an allegation wholly ignores the fact that it is difficult to predict how the other ingredients in the formulation would affect the behavior of the active agent. In other words, even assuming, arguendo, that the exemplary antifungal agents described in Samour and the 2-aminothiazole compounds described in Ippen were functionally equivalent, those skilled in the art would not have been able to predict that using the 2-aminothiazoles in combination with the various particular ingredients provided in Samour would be beneficial, and thus, no reasonable expectation of success would have existed.

The examiner respectfully disagrees with applicant's assertions partly because of the rebuttal arguments set forth above by the examiner because applicant repeats the same arguments

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as set forth above in this section as well. The examiner also respectfully disagrees with applicant's assertions of predictability because, absent of evidence to the contrary, the other ingredients in the composition of Samour are conventionally known film forming agents, plasticizers, and permeation enhancers which are expected to behave the same independent of the type of the antifungal agent. The burden is on Applicant to demonstrate that well-known film formers, plasticizers, and permeation enhancers can affect the substitution of one antifungal agent with another. Furthermore, in the instant case one of ordinary skill in the art would have had a reasonable expectation of success in combining Samour et al. and Ippen et al., because Ippen et al. teach that the pharmaceutical composition that contains an antifungal agent can be used for the treatment prevention, amelioration and/or cure of mycoses (column 21, lines 26-27) either dermatomycoses and systemic mycoses (column 19, lines 32-33), which includes nails and also Samour et al. teach a nail lacquer composition that contains an antifungal agent.

Applicant also asserts that based on the structures of 2-aminothiazoles recited by the pending claims, those skilled in the art would not have expected that the compounds would be compatible with polar ingredients, some of which are used in the formulations described in Samour. To be more specific, those skilled in the art would have expected that the 2-aminothiazole compounds would bind to those polar ingredients, which would result in inactivation. In this regard, a post-priority reference indeed confirms that Abafungin, an antifungal agent used throughout the examples provided in the current specification, "exerts a fungicidal activity preferably in defined minimal media or slightly enriched liquid media at a pH range of 4.0-5.5." (See Borelli et al., Chemotherapy, 54:245-259 (2008), a copy of which is attached hereto as Exhibit A, at page 251, left column). Despite this expectation, it was

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surprisingly and successfully demonstrated that Abafungin, in the presence of polar ingredients recited by the current claims, could be used to substantially improve the symptoms of a fungal infection within 45 days of treatment, and that it is likely to completely cure a fungal infection within 100 to 50 days after the beginning of the treatment. (Specification, page 15). Thus, Applicant respectfully submits that this unexpected result is sufficient to rebut any presumption of obviousness, and thus, requests that this rejection be withdrawn.

The examiner respectfully disagrees with applicant's assertions because the examiner sees nowhere in Borelli et al. how abafungin is affected by the presence of film forming agent, plasticizer, and permeation enhancers. The examiner finds nowhere in Borelli et al. the connection between polarity and the activity of abafungin. The examiner notes the effect of sulfuric acid which is a conventionally known oxidizing agent (see table 6) and also the effect of pH on the activity of abafungin (see table 8). The examiner has not found the teachings of the effect of polarity and activity of abafungin in Borelli et al., and applicant has not pointed out where this connection is taught, if at all.

The film forming agents, plasticizers, and permeation enhancers taught by Samour et al. are expected to be compatible with abafungin in the absence of evidence to the contrary. Therefore, the results presented in the specification page 15 are clearly expected by one of ordinary skill in the art based on the teachings of Samour et al. Furthermore, applicant relying upon comparative showing of unexpected results to rebut *prima facie* case must compare his claimed invention with closest prior art. See, *In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978); *Ex parte Humber*, 217 USPQ 265 (Bd. App.1961). Additionally, showing unexpected results over one of two equally close prior art references will not rebut a *prima facie*

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obviousness unless the teachings of the prior art references are sufficiently similar to each other that the testing of one showing unexpected results would provide the same information as to the other. See, *In re Johnson*, 747 F.2d 1456, 1461, 223 USPQ 1260, 1264 (Fed. Cir. 1984).

Applicants have not demonstrated how their product is patentably distinct from the cited prior art and the claims, as currently written, do not distinguish the instant invention over the prior art. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the cited references.

Claims 1-2 and 4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Samour et al. (US Patent No. 6,224,887) in view of Ippen et al. (US Patent No. 4,956,370) and Wohlrab et al. (US Patent No. 6,719,986), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicant's arguments filed on 04/20/2010 have been fully considered but they are not persuasive. Additionally, the exhibits and arguments has been fully considered but are not persuasive.

Applicant argues that claims 1-2 and 4 are unobvious and patentable for the reasons same as those discussed above in connection with Samour and Ippen. In addition, Applicant respectfully submits that claim 4 is separately patentable because "the use of hyaluronate lyase

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as permeation enhancing agent" does indeed provide patentable distinction to claim 4 over prior art.

The examiner respectfully disagrees with applicant's assertions directed to the arguments directed to Samour and Ippen, as set forth above, for the reasons set forth above. The use of hyaluronate lyase as permeation enhancer does not provide patentable distinction over the prior art because the Wohlrab et al. clearly teach that hyaluronate lyase as a penetration enhancing agent in topical agents (see Abstract).

Applicant argues that Wohlrab teaches that hyaluronate lyase is a skin penetration enhancer. Yet, Samour, the primary reference cited in the Office Action, discloses that "solvents with proven efficacy as skin 'penetration enhancers' show little promise as enhancers of nail permeability." (Samour, col. 2, lines 39-47) (emphasis added). Indeed, this is precisely why Samour provides specific permeation enhancers, i.e., C7-C 14-hydrocarbyl substituted 1,3-dioxolane, C7-C H-hydrocarbyl substituted 1,3-dioxane and CT-Ci4-substituted acetal, for use in its formulations. Thus, in view- of the fact that Wohlrab teaches hyaluronate lyase as a skin penetration enhancer, Samour would have taught those skilled in the art away from using hyaluronate lyase as a permeation enhancer in nail lacquer formulation.

The examiner respectfully disagrees with applicant's assertions because applicant resorted to attacking the references individually while the rejection is based on the combined teachings of the references. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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Additionally, the examiner respectfully disagrees with applicant's assertions because hyaluronate lyase is not a solvent permeation enhancer rather it is an enzyme. Therefore, the teaching cited by applicant in Samour et al. does not necessarily exclude the use of hyaluronate lyase.

Additionally, the teaching cited by applicant from Samour et al. has nothing to do with conventionally known permeation enhancers in a nail polish composition rather they are explaining that solvents that are found to be effective as skin permeation enhancers has shown little promise on nail plate permeability.

Applicant has not demonstrated how the claimed product is patentably distinct from the cited prior art and the instant claims, as currently written, do not distinguish the instant invention over the prior art. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a) for at least the reasons set forth of record and herein.

Claims 1-2, 11, and 14-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Samour et al. (US Patent No. 6,224,887) in view of Ippen et al. (US Patent No. 4,956,370) and Gyurik (WO 01/60325, IDS reference), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicant's arguments filed on 04/20/2010 have been fully considered but they are not persuasive.

Applicant argues that claim 11, which depend from claim 1 or 2, cannot be obvious for the reasons same as those discussed above in connection with claims 1 and 2. The examiner

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respectfully disagrees with applicant's assertions by incorporating the rebuttal arguments set forth above by reference in this section as well since applicant also cited the same reasons set forth above. *Applicant further argues that claims 11 and 14-15 are not obvious over the combination of references cited in the Office Action because the formulation described in Gyurik employs clotrimazole as an active agent, which is completely different from the currently claimed 2-aminothiazole compounds. Therefore, in view of the fact that those skilled in the art would have thought that 2- aminothiazoles would not be compatible with polar ingredients (such as Eudragit and oxacyclohexadecan-2-one) due to the potential binding issue discussed above, there would have been no reason to "incorporate the specific types of" ingredients described in Gyurik. In fact, Applicant respectfully submits that there would have been ample reason not to use the specific types of ingredients described in Gyurik in view of the potential binding issue.*

The examiner respectfully disagrees with applicant's assertions because applicant resorted to attacking the references individually while the rejection is based on the combined teachings of the references. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner also incorporates all the rebuttal arguments set forth above regarding the issue of compatibility of 2- aminothiazoles with polar agents in this rejection.

Applicant further argues that Samour's teaching that "solvents with proven efficacy as skin 'penetration enhancers' show little promise as enhancers of nail permeability" would have

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discouraged those skilled in the art from using, for example, oxacyclohexadecan-2-one (a known skin penetration enhancer) in nail lacquer formulation.

The examiner respectfully disagrees with applicant's assertions because applicant has not substantiated the assertions with objective evidence. Gyurik rebuts applicant's assertion by providing evidence that oxacyclohexadecan-2-one is conventionally known to be used as permeation enhancers in nail lacquer compositions (see examples 1-3 and 5 paragraphs 0058-0061 and 0063).

Applicants have not demonstrated how their product is patentably distinct from the cited prior arts nor do the claims as currently written distinguish the instant invention over the prior arts. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Conclusion

Claims 1-2, 4, 6, and 9-15 are pending and remain rejected. Claims 3, 5, and 7-8 are cancelled. This Office Action is FINAL. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

6/28/10

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647